

REMARKS

The amendments set out above and the following remarks are believed responsive to the points raised by the Office Action dated February 13, 2008. Reconsideration is respectfully requested.

Claims 17-23 have been canceled, and claims 24-30 have been added. New claims 24-30 are identical to previously pending claims 17-23 except that claim 24 now defines a method of treating inflammation *and pain*. The specification has been amended to add a reference to the continuing data to which the instant application claims benefit from. No new matter has been added, the basis for these amendments may be found within the original specification and claims.

Claim 17 was objected to because the amendment filed on 8/28/07 cancelled claim 17 and added new claim 17. With this amendment, it is believed that the objection has now been overcome.

Claim 17 was rejected under 35 U.S.C. §102 as anticipated by U.S. Patent No. 3,840,597 to Moore et al. (hereinafter referred to as "the '597 patent"). Claims 17-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '597 patent in view of U.S. Patent No. 5,756,546 to Pirotte et al. (hereinafter referred to as "the '546 patent"). Each of these rejections is separately and respectfully traversed.

The pending claims are directed to a method of treating inflammation and pain comprising administering an anti-inflammatory analgesic drug comprising a compound of formula (I) (see claim 24). According to the Office Action, the '597 patent discloses a pharmaceutical composition comprising the compound of formula (I) and a method for controlling inflammation in mammalian tissue by using the compound thereof at lines 61-69 of column 1, and line 19-21 of column 13. Applicants respectfully disagree.

As an initial point, column 1, lines 61-69 of the '597 patent it is disclosed that it is "an *object* of the present invention to provide compounds which are anti-inflammatory agents" (emphasis added) and that it is "a further *object* of the invention to provide a method for

controlling inflammation in mammalian tissue" (emphasis added). Merely disclosing that it is an object to achieve a particular result does not disclose that the result has been achieved.

Furthermore, while the '597 patent does identify some compounds as anti-inflammatory agents, the '597 patent does not teach that the compound of Formula I is an anti-inflammatory agent, as further explained below and in the attached Declaration of Professor Wu Zuze.

At lines 19-21 of column 13, the '597 patent merely discloses that 2-(4-methoxyphenoxy)-4-nitromethane-sulfonanilide (i.e., the compound of Formula I) is a starting material to produce 2-(4-hydroxyphenoxy)-4-nitro-methanesulfonanilide. The '597 patent does not disclose using the specific compound of formula (I) as an anti-inflammatory agent or analgesic or a method of controlling inflammation and pain using the specific compound of formula I.

The '597 patent discloses a generic chemical formula with numerous substituents that may each comprise numerous alternatives, and thus a vast number, e.g., on the order of 12,000 compounds are encompassed. The '597 patent alleges that these compounds are active anti-inflammatory agents and some are analgesic. However, the '597 patent only provides data showing the anti-inflammatory activity for those compounds identified as "preferred" (see e.g., column 6, line 55 to column 7, line 8). The "preferred compounds" are either unsubstituted or substituted with a halogen atom on the phenyl ring on the right hand side. In contrast, the compound of formula I is substituted with a methoxy group on the right hand phenyl ring. As set forth in the attached Declaration, one skilled in the art would believe that such a structural difference would likely lead to different activity. Accordingly, one skilled in the art reading the '597 patent would not be taught that compounds including substituents other than those in the "preferred compounds" possess anti-inflammatory activity.

Furthermore, as set forth in the attached Declaration, not all compounds within the class are active anti-inflammatory agents. Tests results for two compounds within the broadly disclosed class were tested and failed to show any anti-inflammatory activity. Thus, one skilled in the art could reasonably expect different compounds within the class to possess different

activities.

Additionally, the '597 patent does not provide any data showing analgesic activity for any of the compounds within the class. Indeed, the '597 patent merely discloses that "some are analgesic". It is well known to those skilled in the art that not all anti-inflammatory agents possess analgesic activity. Since the '597 patent discloses a vast number of compounds, e.g., on the order of 12,000, the '597 patent merely discloses that "some of" over 12,000 compounds are analgesic, without any further guidance as to which compounds may be analgesic. According to MPEP 2131.02, a generic chemical formula will anticipate a claimed species covered by the formula when the species can be 'at once envisaged' from the formula". The MPEP further explains, "When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte a*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). In *In re Petering*, the prior art disclosed a generic chemical formula "wherein X, Y, Z, P, and R^{*} represent either hydrogen or alkyl radicals, R a side chain containing an OH group." the court held that this formula, without more, could not anticipate a claim to 7-methyl-9-[d, l⁻-ribityl]-isoalloxazine because the generic formula encompassed a vast number and perhaps even an infinite number of compounds. Similarly, in the present case, the disclosure that that *some of* the more than 12,000 compounds encompassed by the '597 patent possess analgesic activity would not teach that the specific compound of formula I possesses analgesic activity.

Accordingly, the '597 patent fails to teach that compounds other than the "preferred compounds", i.e., compounds containing different substituents, possess anti-inflammatory activity and fails to teach any compounds possessing analgesic activity. Since the '597 patent does not disclose using the present compound to treat inflammation and pain and does not teach that the present compound possesses anti-inflammatory or analgesic activity, the '597 cannot anticipate the present claims. Therefore, it is respectfully requested that the rejections be withdrawn.

10/541,058
In re SUN, et al.

The method of the present claims is patentably distinct from that of the '597 patent for the reasons set forth above. The fact that the '546 patent may teach a water-soluble nimulsulide-L-lysine salt is of no importance. The '546 patent simply does not cure the deficiencies of the '597 patent, and therefore, the combination also fails to render the present invention obvious.

In view of the amendment and remarks recited herein, the application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

Shannon D. Schemel

Shannon D. Schemel
Registration No. 47,926

Berenato, White & Stavish
6550 Rock Spring Drive, Suite 240
Bethesda, MD 20817
Tel. (301) 896-0600
Fax. (301) 896-0607

Date: Aug. 7, 2008